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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/796,357

Applicant(s)

SHEETZ, RICHARD HALL

Examiner

Keith O. Robinson, Ph.D.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 08 June 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

1. Claims 1, 6, 22, and 23 are objected to for their inclusion of blanks (____). It is assumed that the blanks will be replaced by an ATCC Accession Number.
2. Claim 1 is objected to for the omission of "A" before "seed of cotton line..." because only a single invention can be claimed. This objection can be obviated by the amending the claim to read --A seed of cotton line...--.
3. Claim 4 is objected to for the omission of "A" before "protoplasts produced from..." and the use of "protoplasts" because only a single invention can be claimed. These objections can be obviated by amending the claim to read --A protoplast-- before "produced from...".
4. Claim 5 is objected to for the phrase "...the tissue culture are from...". This phrase appears to unduly limit the invention to a first generation tissue culture. It is recommended that Applicant amend the claim to read --...the tissue culture are produced from...--.
5. Claim 20 is objected to the inclusion of the phrase "...the cotton plant of claim 2 with a transgene encoding a protein selected from the group consisting of stearyl ACP desaturase, ...". The specification only teaches transformation of a plant with an antisense gene of stearoyl-ACP desaturase (see page 23, paragraph 00116). In addition, the term "stearoyl-ACP desaturase" in the specification claims an old term for the enzyme of EC 1.14.99.6, which has been changed to "stearyl-ACP desaturase" for

Art Unit: 1638

EC 1.14.19.2. Either term would be proper in the claims, but the claims and the specification should be consistent in the spelling. These objections can be obviated by amending the claim by deleting "stearyl-ACP desaturase," after "of" and before "fructosyltransferase" and inserting —or encoding an antisense of stearyl-ACP desaturase—after the word "enzyme" and before the period (.) at the end of the claim.

Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to seed of cotton line PM 2168 RR, methods of using said seed, and parts thereof.

Since the seed is essential to the claimed inventions, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit

Art Unit: 1638

of 2500 seed of each of the claimed embodiments is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807) and,
- (e) the deposit will be replaced if it should ever become inviable.

It is noted that Applicants intend to deposit seed of this invention (see page 31 of the specification), but the conditions under which the deposit will be made is unclear. There is no indication in the specification as to the duration that the deposit will be maintained, the viability of the biological material at the time of deposit, or the replacement of inviable seeds.

Applicant is required to make the necessary corrections.

8. Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are broadly drawn hybrid cotton seed and seed derived from said hybrid cotton seed.

The specification does not describe the other cotton plant or plants that are to be crossed with PM 2168 RR nor is there a description of their genetic, morphological, and/or physiological background. It is known in the art that any plant derived from the crossing of two different plants will be an F1 hybrid plant that is heterozygous at all loci, therefore, the hybrid plant will contain 50% of the alleles from the PM 2168 RR cotton plant and 50% of the alleles from the other cotton plant. The PM 2168 RR cotton plant, as well as its seeds and parts thereof, is the claimed invention, so a plant that contains only 50% of the alleles of the PM 2168 RR cotton plant is not the same as the claimed PM 2168 RR cotton plant, which would have 100% of its alleles. Furthermore, claim 9

Art Unit: 1638

reads on an additional generation of outcrossing to a non-PM 2168 RR cotton parent so that seed with as little as 25% of the PM 2168 RR alleles would be produced. Moreover, the genetic, morphological, and/or physiological characteristics of the claimed hybrids are not described in the specification. Since the claimed invention is derived from crossing PM 2168 RR with any cotton plant, there could conceivably be hundreds of hybrids, each with different genetic, morphological, and/or physiological characteristics due to each having different "other" parents and the specification does not describe these hundreds of hybrids.

The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern US Patent 5,850,009, column 4, lines 41-46); therefore, Applicant has not described the myriad of different hybrids that may be produced from the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the

absence of knowledge as to what that material consists of, is not description of that material". Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

9. Claims 8-9 and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

Art Unit: 1638

to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are broadly drawn hybrid cotton seed and seed derived from said hybrid cotton seed.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The specification does give any guidance as to the other cotton plant or plants that are to be crossed with PM 2168 RR nor is there any guidance as to their genetic, morphological, and/or physiological background. It is known in the art that any plant derived from the crossing of two different plants will be an F1 hybrid plant that is heterozygous at all loci; therefore, the hybrid plant will contain 50% of the alleles from the PM 2168 RR cotton plant and 50% of the alleles from the other cotton plant. The PM 2168 RR cotton plant, as well as its seeds and parts thereof, is the claimed invention, so a plant that contains only 50% of the alleles of the PM 2168 RR cotton plant is not the same as the claimed PM 2168 RR cotton plant, which would have 100% of its alleles. Furthermore, claim 9 reads on an additional generation of outcrossing to a non-PM 2168 RR cotton parent so that seed with as little as 25% of the PM 2168 RR alleles would be produced. Moreover, the genetic, morphological, and/or physiological

Art Unit: 1638

characteristics of the claimed hybrids are not described in the specification. Since the claimed invention is derived from crossing PM 2168 RR with any cotton plant, there could conceivably be hundreds of hybrids, each with different genetic, morphological, and/or physiological characteristics due to each having different "other" parents and the specification does not describe these hundreds of hybrids in terms of their traits, or provide any guidance regarding their use and therefore, it would not enable one skilled in the art to make and/or use the claimed invention.

The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46). The nature of the art at the time of Applicant's invention was such that one of skill in the art could not reasonably predict what the product of a cross between two inbred parental plants would be without a reduction to practice. The art teaches that "Even if an inbred in hybrid combination has excellent yield (a desired characteristic), it may not be useful because it fails to have acceptable parental traits such as seed yield, seed size, pollen production, plant height, etc." (Carlone, U.S. Patent 5,763,755, column 2, lines 11-14). The art teaches that based on the number of segregating genes, the frequency of occurrence of any individual with a specific genotype is less than 1 in 10,000 and that even if the entire genotype of the parents has been characterized and the desired phenotype is known, only a few if any individuals having the desired genotype may be

Art Unit: 1638

found in a large F_2 or S_0 population and that typically the genotype of neither the parents nor the desired genotype is known in detail (see Segebart, U.S. Patent 5,304,719, in particular the paragraph spanning columns 2-3). The art also teaches that the number of genes affecting the trait of primary economic importance can be in the range of 10-1000 and that inbred lines which are used as parents for breeding crosses differ in the number and combination of these genes (Segebart, U.S. Patent 5,367,109, column 2, lines 60-64). Segebart ('109) also teaches that one of the largest plant breeding programs in the world does not have a sufficiently large breeding population to be able to rely upon "playing the numbers" to obtain successful research results and that plant breeders use their skills, experience and intuitive ability to select inbreds having the necessary qualities (column 4, 1st and 2nd paragraphs). Hence, given the fact that one of skill in the art cannot reasonably predict the number of genes that affect the traits of the parental inbred lines of a inbred cotton plant, it is unclear how one of skill in the art could reasonably predict how to make and use the claimed cotton plants and methods of making a cotton plant using a second or filial non-exemplified cotton plant produced from Applicant's exemplified inbred cotton plant.

Given the lack of guidance in Applicant's specification regarding a multitude of non-exemplified hybrids and the breadth of the claims, one skilled in the art would not be able to make and/or use the inventions claimed without undue experimentations.

Claim Rejections - 35 USC § 102/103

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 8-9 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallace et al (Crop Sci. 42:2216-2217, 2002).

13. The claims read on F2 progeny, including segregating progeny with 100% of non-PM 2168 RR alleles; therefore, the claim reads on any cotton plant or seed with any alleles at any locus. The claimed method of making the plant or seed would not confer a unique property to the resultant non-PM 2168 RR cotton plant or seed.

14. Wallace et al teach a cotton plant and seeds thereof (see page 2216, second column to page 2217, end of the first column).

15. Wallace et al do not teach cotton plants or seeds derived from the cross of cotton line PM 2168 RR with another cotton plant.

16. The cotton plant or seed taught by the prior art differs from the claimed cotton plant or seed in their method of making, namely by the use of different parental material. However, the method of making the claimed cotton plant would not distinguish it from the prior art cotton plant. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Conclusion

17. Claims 1-8 and 10-27 are deemed free of the prior art, given the failure of the prior art to teach or suggest an exemplified cotton plant which possesses a unique genetic complement and unique collection of traits as that of cotton line PM 2168 RR, or methods of using said cotton line.

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is

Art Unit: 1638

571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

February 16, 2005

DAVID H. KRUSE, PH.D.
PATENT EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written in a cursive style.